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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,447	05/18/2007	Alastair Edwin McAuley	1171/45167/170-PCT-US	6959
279 7590 07/23/2009 Trexler, Bushnell, Giangiorgi, Blackstone & Marr, Ltd. 105 West Adams Street Suite 3600 Chicago, IL 60603			EXAMINER YOUNG, RACHEL T	
			ART UNIT 4138	PAPER NUMBER
			MAIL DATE 07/23/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,447	Applicant(s) MCAULEY ET AL.	
	Examiner RACHEL T. YOUNG	Art Unit 4138	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/14/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendment

1. Receipt is acknowledged of applicants preliminary amendments, which papers have been placed of record in the file.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The disclosure is objected to because of the following informalities: Page 2, line 3 recites "goes some way", which appears to be a misspelling of "gives some way". Page 2, line 5 recites "Accordingly in a", which appears to be a missing a comma after "Accordingly,". Page 7, line 25 recites "portion 3", which appears to be a misspelling of "portion 303".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon et al. (U.S. Patent Pub. 2003/0217746 A1) in view of Ging et al. (U.S. Patent Pub. 2003/0196658 A1).

As to claim 1, Gradon teaches a cushion (1104) (Fig. 18) for a patient interface adapted to supply gas (Page 1, ¶ 2, ll. 5-6) to a patient comprising a cushion body (1110) (Fig. 19). Gradon is silent regarding an outer cover, wherein said body and cover are substantially formed of the same elemental material. However, Ging teaches a facemask with an outer cover (205) (Fig. 24d) ("membrane" Page 13, ¶ 174-175) that is made of polyurethane (Page 13, ¶ 174, ll. 14). Gradon teaches that a body is also made of polyurethane (Page 3, ¶ 56, ll. 3-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gradon's device to include an outer cover that is made of polyurethane, which is the same material as the body, as taught by Ging, for the purpose of allowing rotation of the mask relative to a patient's face (Page 13, ¶ 174, ll. 3-4) and ease of manufacturing.

As to claims 2-3, Gradon teaches that the elemental material of a cushion is polyurethane (Page 3, ¶ 56, ll. 3-4), and that a cushion body is formed in polyurethane foam (Page 3, ¶ 56, ll. 3-4).

As to claims 4-5, Gradon discloses the claimed invention except wherein the outer cover of a cushion is formed in polyurethane film, and that the cover is adhered to the cushion body. However, Ging teaches a facemask in which the outer cover of a cushion is formed in polyurethane film (Page 13, ¶ 174, ll. 14), and that the cover is

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adhered to the cushion body (205) (Fig. 24d) ("sealing structure" Page 12, ¶ 171, ll. 2-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gradon's device such that the outer cover of a cushion is formed in polyurethane film, and that the cover is adhered to the cushion body, as taught by Ging, for the purpose of allowing for ease of manufacturing and providing a sufficient seal for the facemask.

As to claim 7, Gradon teaches that the cushion body includes an attachment (108) (Fig. 2) adapted to engage a mask.

As to claim 8, Gradon teaches a cushion (1104) (Fig. 18) for a patient interface adapted to supply gas to a patient (Page 1, ¶ 2, ll. 5-6) comprising a cushion body (1110) (Fig. 19) having an outer sealing sheath (1112) (Fig. 19) (Page 3, ¶ 56, ll. 2-3) wherein said cushion body is detachable from said outer sheath and said patient interface (Page 3, ¶ 58, ll. 1-3). Gradon is silent regarding an outer cover. However, Ging teaches a facemask with an outer cover (200) (Fig. 24a) ("support structure" Page 12, ¶ 171, ll. 5-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gradon's device to include an outer cover, as taught by Ging, for the purpose of providing additional structural support.

As to claims 9-10, Gradon is silent regarding that a cushion body and said outer sealing sheath are formed of the same elemental material, and that elemental material is silicone. Gradon does teach that the cushion body is silicone (Page 3, ¶ 62, ll. 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Gradon's device such that the outer sealing sheath is also made of

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silicone, for the purpose of providing an ease of manufacturing, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon/Ging in view of Colvin et al. (U.S. Patent No. 5518802).

As to claim 6, Gradon discloses the claimed invention except wherein the cushion body is assembled from more than one moulded component. However, Colvin teaches a cushion body that is assembled from more than one moulded component (Col. 7, ll. 27-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gradon's device such that the cushion body is assembled from more than one moulded component, as taught by Colvin, for the purpose of providing greater strength in the cushion structure (Col. 7, ll. 29).

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon et al. (U.S. Patent Pub. 2003/0217746 A1) in view of Colvin et al. (U.S. Patent No. 5518802).

As to claims 11-13, Gradon teaches a mask (2) (Fig. 1) adapted to deliver gas to a patient (Page 1, ¶ 2, ll. 5-6) comprising a cushion body (1104) (Fig. 18). Gradon is silent regarding wherein at least a portion of the cushion body thereof has a plurality of adjacent voids, and wherein each of the voids has a hexagonal cross section, and wherein each of the voids has a square cross section. However, Colvin teaches a cushion wherein at least a portion thereof has a plurality of adjacent voids (27) (Fig. 1),

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wherein each of the voids has a hexagonal cross section (Fig. 1), and wherein each of the voids has a square cross section (Fig. 3A). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gradon's device such that at least a portion of a cushion body thereof has a plurality of adjacent voids, wherein each of the voids has a hexagonal cross section, and wherein each of the voids has a square cross section, as taught by Colvin, for the purpose of providing good shock absorbing protection (Col. 7, ll. 30-33).

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon/Colvin in view of Ging et al. (U.S. Patent Pub. 2003/0196658 A1).

As to claim 14, Gradon teaches a cushion body (1104) (Fig. 18) having an outer sealing sheath (1112) (Fig. 19) (Page 3, ¶ 56, ll. 2-3). Gradon is silent regarding an outer cover. However, Ging teaches a facemask with an outer cover (200) (Fig. 24a) ("support structure" Page 12, ¶ 171, ll. 5-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gradon's device to include an outer cover, as taught by Ging, for the purpose of providing additional structural support.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL T. YOUNG whose telephone number is (571) 270-1481. The examiner can normally be reached on Monday through Friday, 8 AM-5PM, Est., alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on 571-272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T. Y./
Examiner, Art Unit 4138

/Quang D. Thanh/
Supervisory Patent Examiner, Art
Unit 4138